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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC **(first reading)** - Adoption of the legislative act

1. On 27 February 2023 the Commission submitted its proposal[1] to the Council. The legal basis for the draft Regulation is Article 114 and Article 168(4), point (c).

2. The Committee of the Regions was consulted and decided not to issue an opinion**.**

3. The European Economic and Social Committee delivered its opinion on 27 April 2023[2].

4. On 9 May 2023 the European Parliament adopted its position at first reading on the Commission proposal. The outcome of voting in the European Parliament reflects the compromise agreement reached between the institutions and should, therefore, be acceptable to the Council[3].

1 6928/23.
2 Not yet published in the OJ.
3 9196/23.

5. The Permanent Representatives Committee is therefore asked to confirm its agreement and to suggest that the Council approve the European Parliament's position, as set out in PE-CONS 20/1/23 REV 1, as an "A" item at a forthcoming meeting.

6. If the Council approves the European Parliament's position, the legislative act will be adopted.

After being signed by the Presidents of the European Parliament and of the Council, the legislative act will be published in the *Official Journal of the European Union*.